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Notices

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Public Health Service (PHS)
Food and Drug Administration (FDA)

[Docket No. 94E-0315]

Determination of Regulatory Review Period for Purposes of Patent Extension; CPI (R) Ventak (R) PRx (R) AICD System

59 FR 58848

DATE: Tuesday, November 15, 1994

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CPI (R) Ventak (R) PRx (R) AICD System and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device CPI (R) Ventak (R) PRx (R) AICD System. CPI (R) Ventak (R) PRx (R) AICD System is indicated for the treatment of patients with ventricular fibrillation and/or ventricular tachyarrhythmias who are at high risk of sudden cardiac death. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CPI (R) Ventak (R) PRx (R) AICD System (U.S. Patent No. 4,407,288) from Cardiac Pacemakers, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated September 21, 1994, advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of CPI (R) Ventak (R) PRx (R) AICD System represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CPI (R) Ventak (R) PRx (R) AICD System is 1,306 days. Of this time, 398 days occurred during the testing phase of the regulatory review period, while 908 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: November 21, 1990. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective on November 21, 1990.

2. The date an application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): December 23, 1991. The applicant claims December 20, 1991, as the date the premarket approval application (PMA) for CPI (R) Ventak (R) PRx (R) AICD (PMA P910077) was initially submitted. However, FDA records indicate that PMA P910077 was submitted on December 23, 1991.

3. The date the application was approved: June 17, 1994. FDA has verified the applicant's claim that PMA P910077 was approved on June 17, 1994.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 394 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 17, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before May 15, 1995, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-2, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single

copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 3, 1994.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 94-28064 Filed 11-14-94; 8:45 am]

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